

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION OPIATE
LITIGATION**

This document relates to:

Jennifer Artz, et al. v. Endo Health Solutions Inc., et al.
Case No. 1:19-OP-45459

Michelle Frost v. Endo Health Solutions Inc. et al.
Case No. 1:18-OP-46327

Salmons v. Purdue Pharma L.P., et al.
Case No. 1:18-OP-45268

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**DEFENDANTS' SURREPLY IN OPPOSITION TO NAS PLAINTIFFS'
MOTION FOR CLASS CERTIFICATION**

In their reply in support of their motion for class certification, Plaintiffs make several new factual and legal assertions. This surreply addresses just three of them:

- Plaintiffs offer yet another new class definition, requiring “(1) guardianship over (2) a child diagnosed with NAS (3) whose birth mother had a prescription for opioids prior to that birth, or alternatively and more narrowly, (4) a prescription during pregnancy,” Dkt. 3555 at 2-3;
- Plaintiffs belatedly offer a new declaration from their expert, Dr. Anand, allegedly reflecting Dr. Anand’s recent review of individual medical records, from which he now purports to opine that the children of the proposed class representatives suffered from NAS;
- Plaintiffs introduce a new request for the certification of an issue class (although without specifying the issues on which certification is sought).¹

¹ Plaintiffs also newly assert in their reply that their “conspiracy allegation is the centerpiece of this litigation.” Dkt. 3555 at 5. This argument fails for the reasons set out in Defendants’

It is black letter law that arguments raised for the first time in a reply brief are waived. *See Hunt v. Big Lots Stores, Inc.*, 244 F.R.D. 394, 397 (N.D. Ohio 2007) (collecting Sixth Circuit cases). Likewise, Rule 26, Rule 37(c), and the Court’s scheduling order all bar parties from submitting belated expert opinions in support of motion papers. *See, e.g., Hobart Corp. v. Dayton Power & Light Co.*, 2020 WL 5106743, at *3-4 (S.D. Ohio Aug. 31, 2020); *Moonbeam Capital Investments, LLC v. Integrated Construction Solutions, Inc.*, 2020 WL 1502004, at *6 (E.D. Mich. Mar. 30, 2020); *see also* Opinion & Order, Dkt. 2131, at 3-4 (striking expert affidavit when untimely disclosed in support of motion instead of on schedule set by Court). But even if the Court were to consider these new arguments and opinions, Plaintiffs still do not meet their burden to prove that their proposed class meets the requirements of Rule 23. *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 275 (2014). Indeed, Plaintiffs’ shifting positions further underscore why this class should not be certified.

Plaintiffs’ New Class Definition

Plaintiffs’ motion for class certification sets forth their proposed class and subclass definitions multiple times, and at length. *See* Dkt. 3066 at 1-2, 5, 10-12; Dkt. 3066-1 at 4-6; Dkt. 3066-2 at 1, 4, 7, 9-10. There were numerous contradictions and inconsistencies among those definitions, but in *every instance*, Plaintiffs explicitly described their proposed class as limited to guardians of children “medically diagnosed with ***opioid-related* NAS *at or near birth***.” *See id.* (emphases added). Plaintiffs have repeatedly stressed that the class they seek consists of

Opposition. Allegations of conspiracy are insufficient for purposes of the Rule 23 factors to overcome the fact that the birth mothers of class members’ children consumed opioids that were manufactured, distributed, and dispensed by different Defendants. *See* Dkt. 3536 at 28-29, 39-40, 48 n.29, 52-53. Moreover, not all proposed class representatives have even *pled* conspiracy against all of the Defendants, under either federal or state law. *Id.* at 8, 40-41.

guardians of “infants born addicted to opioids from *in utero* exposure,” among other limitations. *See, e.g.*, Dkt. 3066 at 2 n.3. But in response to Defendants’ opposition, which demonstrated that the children of the proposed class representatives were not “medically diagnosed with opioid-related NAS” at birth, Plaintiffs bizarrely accuse Defendants of “improperly graft[ing] an additional requirement onto the class definition.” *Id.* at 3.

Recognizing that their class representatives do not satisfy their originally proposed class definitions, Plaintiffs now seek to abandon those definitions and switch to the new class definition quoted above. Significantly, their new proposed definition eliminates the requirement that the child’s NAS diagnosis have any connection whatsoever to the birth mother’s use of opioids — the reinvented definition presents the birth mother’s use of opioids and the child’s NAS diagnosis as two entirely siloed requirements. It also eliminates the requirement that the NAS diagnosis be “at or near birth,” thereby allowing belated purported diagnoses for litigation purposes. Furthermore, Plaintiffs have not stated whether they are abandoning the other components of their prior class definitions, including that the children in question be born after March 16, 2000; that the “opioids or opiates [be] manufactured, distributed, or filled by a Defendant or Purdue entity”; that children not have been “treated with opioids after birth, other than for pharmacological weaning”; and that the guardians not be political subdivisions. Dkt. 3066 at 1-2.²

² Nor have Plaintiffs addressed how this new definition relates to the various proposed classes, subclasses, and state-specific classes set forth in their original motion.

Plaintiffs make no effort to explain how the requirements of Rule 23 could be satisfied if these significant limitations are removed.³ In fact, Plaintiffs' proposed redefined classes would have *greater* challenges under Rule 23. For example, in their opening brief Plaintiffs argued that all proposed class members would satisfy the elements of medical monitoring claims, such as the level of substance exposure and increased risk as a result of that exposure, because any child meeting the class definition would have experienced and been diagnosed with NAS related to opioid exposure. *See* Dkt. 3066-1 at 20-21, 36-37. Even if this argument had merit (which it does not, as demonstrated in Defendants' opposition), Plaintiffs' new class definition would abandon it, as Plaintiffs' class would include guardians of children whose NAS diagnosis had nothing to do with opioid exposure. Plaintiffs' redefined class would even include the guardian of a child whose birth mother received an opioid prescription in her childhood, did not fill the prescription and never ingested an opioid, and years later had a child diagnosed with NAS related to her use of a *different* substance during pregnancy.⁴ Accordingly, like the originally proposed class definition, the new class definition unquestionably requires individualized evidence to establish each element of a medical monitoring claim against Defendants. And the

³ For example, Plaintiffs fail to explain how a class member could possibly have a claim against these Defendants if the opioids consumed by the birth mother were not marketed, distributed, or dispensed by any of the Defendants, or if the pertinent events occurred so long ago that the statute of limitations necessarily bars recovery.

⁴ Plaintiffs argue that NAS is a diagnosis that is made *only* as a result of *in utero* opioid exposure. Dkt. 3555 at 14-15. This argument is contrary to the overwhelming evidence presented by the experts in this case, including the admission of Plaintiffs' expert Dr. Anand that infants can receive scores on the Finnegan diagnostic scale that lead to an NAS diagnosis without being exposed to opioids *in utero*. Ex. A, Anand Deposition at 266:12-269:18. Dr. Anand also admits that other drugs can cause abstinence syndromes in neonates and that the characteristics of those other abstinence syndromes and abstinence syndrome caused by opioids overlap. *Id.* at 77:13-78:3. And whether any particular infant was correctly diagnosed with NAS or whether that infant's symptoms were caused by another substance would still require case-by-case examination. *See* Dkt. 3523-3, Rubin Report, at 2.

necessity of that individualized evidence precludes findings of typicality, commonality, or adequacy under Rule 23(a), and findings of predominance and superiority or cohesion under Rule 23(b). *See* Dkt. 3536 at 27-35, 46, 56, 58-59.

The “Supplemental” Declaration of Plaintiffs’ Expert Dr. Anand

Plaintiffs offer in support of their reply a new “supplemental” declaration from their expert, Dr. Anand, in which he asserts that Melissa Barnwell, Jacqueline Ramirez, and Ashley Poe “meet the class definition of clients with children suffering from NAS.” Anand Supplemental Decl., Dkt. 3557, at 2. Dr. Anand bases this assertion on a chart in which he assesses whether each child met factors including a “positive” “maternal history” and “medication assisted therapy.” *See id.*

As an initial matter, the declaration is procedurally barred because it is nearly a year late. As required by this Court’s scheduling order, Plaintiffs disclosed their expert reports in support of class certification in December 2019. Dkts. 2738, 2969. Defendants deposed Dr. Anand on January 28, 2020. At that time, Dr. Anand had not reviewed *any* records related to individual proposed class representatives and had not relied on them in reaching his opinion. He testified that the materials served on Defendants before his deposition contained a “complete statement” of his opinions and that he had identified all of the materials on which he intended to rely.⁵ Ex.

⁵ In this regard, Plaintiffs’ assertion that Defendants have not challenged the methodology of Plaintiffs’ experts falls flat. Dkt. 3555 at 21-22. First, Defendants could not have challenged these new opinions of Dr. Anand before now. Second, insofar as Plaintiffs’ experts’ opinions relate to class certification at all — and most of them do not — they support Defendants in acknowledging the variation between individuals that bars class treatment. Defendants reserve the right to challenge the admissibility of these opinions as to the *merits* of Plaintiffs’ claims at the appropriate time.

A, Anand Deposition at 55:23-56:17, 59:3-11. In short, Dr. Anand's tardy supplemental declaration is foreclosed by the scheduling order and Dr. Anand's own testimony.

Moreover, while styled as "supplemental," Dr. Anand's new declaration offers wholly new opinions based on the review of medical evidence Dr. Anand did not previously consider. Plaintiffs never sought leave to supplement Dr. Anand's opinions or otherwise indicated that they would offer him as an expert on the individual medical conditions of each class representative's child. Defendants have had no opportunity to test through cross-examination the accuracy and basis of Dr. Anand's new opinions (much less to offer responsive opinions from their own experts). Moreover, Dr. Anand's declaration fails to identify the basis of these new opinions: It offers no citations to specific medical records and assesses the children on criteria different from those set forth in his prior declaration (which did not include "maternal history" or "medication assisted therapy" criteria). *Compare* Dkt. 3557 at 2 *with* Dkt. 3067-5 at 134. Accordingly, the Court should disregard this untimely filing.

Even if the Court considers Dr. Anand's new report, the opinions set forth in the report fail to demonstrate that the proposed class representatives are members of the class. Neither the criteria set forth in Dr. Anand's initial report nor those reflected in his supplemental report satisfy Plaintiffs' originally proffered class requirement that the children have been "medically diagnosed with opioid-related NAS at or near birth." *See* Dkt. 3536 at 8-9, 21. Nor do they satisfy Plaintiffs' new class requirement that the children simply be "diagnosed" with NAS. And Dr. Anand's proffered *conclusion* about each child ("suffering from NAS") also does not match any of Plaintiffs' varying class definitions. In fact, Dr. Anand's supplemental declaration explicitly admits that the medical records for the child of Jacqueline and Roman Ramirez do *not* contain an NAS diagnosis, although Dr. Anand still claims that the child was "suffering from

NAS.” Dkt. 3557 at 2. Accordingly, Dr. Anand’s new opinions do not render any of these guardians members of either the original proposed class or the new proposed class.

Even more significantly, Plaintiffs’ reliance on expert testimony to purportedly establish that specific children could have been diagnosed as having NAS — by asking Dr. Anand to apply “the published medical literature [and] [his] knowledge, training and clinical experience” to the children’s medical records — *proves* that these cases are unsuitable for class treatment. Class membership must be objectively defined and may not require “individualized fact-finding.” *Romberio v. Unumprovident Corp.*, 385 F. App’x 423, 431 (6th Cir. 2009). Dr. Anand’s need to review and evaluate hundreds of pages of individual medical records is a prime example of individualized fact-finding.

Plaintiffs’ Request for Issue Class Certification

Despite having filed multiple amended complaints and a motion for class certification nearly a year ago, Plaintiffs ask for an issue class to be certified for the first time in their reply. Dkt. 3555 at 40. While Rule 23(c)(4) permits an action “[w]hen appropriate” to be “brought or maintained as a class action with respect to *particular issues*” (emphasis added), Plaintiffs do not identify in their class definitions (or otherwise) any “particular issues” for which they seek certification; nor do they demonstrate how any such issues satisfy the Rule 23 requirements. Instead, they merely purport to cite “example[s]” of issues that they assert “can be resolved once for all class members on the basis of common evidence.” *Id.* This falls far short of satisfying their burden under Rule 23. To support certification of an issue class, Plaintiffs must prove that the selected “particular issue” meets all of the requirements under Rule 23(a) and (b). *See In re Nat’l Prescription Opiate Litig.*, 976 F.3d 664, 775 (6th Cir. 2020); *see also Martin v. Behr Dayton Thermal Prods. LLC*, 896 F.3d 405, 413 (6th Cir. 2018) (requiring predominance and

superiority requirements to be met for issue class). Plaintiffs have made no such showing in the single, conclusory paragraph they devote to this issue.

Moreover, Plaintiffs' "example" issues, unlike those certified in *Martin*, are demonstrably not "questions that need only be answered once because the answers apply in the same way" to each plaintiff. *Martin*, 896 F.3d at 415. For example, Plaintiffs suggest as a possible "issue" for class treatment "the *potential* of exposure to opioids *in utero* to cause harm." Dkt. 3555 at 40 (emphasis added). But that issue cannot be resolved on a class-wide basis. Plaintiffs' own expert Dr. Howard admitted that the potential of opioids to cause particular harms to a fetus varies by factors including the type of harm, the timing of exposure, the duration of exposure, and the genetics and medical history of the mother and father. *See, e.g.*, Howard Deposition, Dkt. 3523-7, at 44:3-45:5, 181:11-182:18, 397:2-18. The potential of exposure to opioids *in utero* to cause harm, therefore, is a question that must be examined for each plaintiff with respect to the opioids involved with that plaintiff's case, the times and quantities in which they were taken, and the particular harms alleged. And even were Plaintiffs to establish that their children's exposure to opioids *in utero* could cause them harm, such a conclusion would prove nothing as to any other, let alone every other, absent class member.

CONCLUSION

Plaintiffs' ongoing revisions to their class definition, supporting evidence, and rationale and continued inability to satisfy the requirements of Rule 23 demonstrate that their claims are fundamentally unsuitable for treatment as a class action. For the reasons set forth in Defendants' opposition to class certification and in the foregoing, Plaintiffs' motion for class certification should be denied.

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